REMARKS

Claims 1-3 and 10 have been amended and Claims 11 and 59 have been canceled without prejudice or disclaimer. Claims 1-8, 10, 48, and 57-58 are pending in the instant application. The amendments to the claims merely serve to clarify the nature of the claims or are fully supported by the specification, for example on page 27, lines 20-23. Thus the amendments do not constitute new matter.

With regard to part (c) of Claims 1-3, Applicants note that the Federal Circuit has recently indicated that a claim which recites a genus of nucleotide sequences based on their hybridization properties "may be adequately described if [the claimed nucleic acid molecules] hybridize under highly stringent conditions to known sequences because such conditions dictate that all species within the genus will be structurally similar." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1327 (Fed. Circ. 2002). Applicants also note that the instant specification describes hybridization at 65°C in a buffer comprising 0.015 M sodium chloride and 0.0015 M sodium citrate as "highly stringent" (*see, e.g.*, page 27, lines 20-23).

The rejections set forth in the Office Action have been overcome by amendment or are traversed by argument below.

1. Claim Objections

The Office Action has objected to Claims 1 and 3 under the assertion that the recitation of "a polypeptide as set forth in any of..." is grammatically incorrect. Applicants disagree with this assertion, but have nevertheless amended Claim 1-3 as suggested by the Office. Applicants contend that these amendments in no way limit or alter the scope of the claims. Applicants therefore request reconsideration and withdraw of the objection to Claims 1 and 3.

2. Claim Rejections Under 35 U.S.C. §101

The Office Action asserts a rejection of claims 1-8, 10, 11, 48, and 57-49 under 35 U.S.C. § 101 as not supported by a substantial or well-established utility. Applicants respectfully traverse this assertion. Applicants first note that claims 11 and 59 have been cancelled, thus obviating their rejection.

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With regard to pending claims 1-8, 10, 48, and 57-58, Applicants are required to demonstrate that the asserted utility is specific and substantial, and if so, whether such asserted utility is credible. Applicants contend that they have met this burden. Under the guidelines of the *Revised Interim Utility Guidelines Training Materials* ("*Training Materials*"), page 9, Applicants, in the absence of a well-established inherent utility, must first make an assertion of utility for the invention. As the Office Action has recognized (page 3), the Applicants have asserted that the claimed nucleic acid molecules may be used to encode polypeptides having B7-like activity.

Next, the assertion of utility must identify a specific utility. The *Training Materials*, on page 5, define a "specific utility" as a utility that is *specific* to the subject matter claimed, as contrasted with a *general* utility that would be applicable to the broad class of the invention. To illustrate the difference between a specific utility and a general utility, the *Training Materials* refer to a claim directed to a polynucleotide whose only asserted utility is that of a gene probe or a chromosome marker, which is a use that all polynucleotide sequences would have, and therefore, is merely a general utility. As applied to the instant application, the claimed subject matter encompasses nucleic acid molecules encoding B7-like polypeptides, while the broad class of the invention is nucleic acid molecules. The present application asserts a utility that not *all* polynucleotide sequences would have, *i.e.*, not *all* polynucleotide sequences could be used to encode B7-like polypeptides. Thus, Applicants contend that the asserted utility is specific to the subject matter claimed, and thus satisfies the first prong of a utility analysis.

Third, the assertion of utility must be substantial. The *Training Materials*, on page 6, define a "substantial utility" as a utility that has a "real world" use. B7-like proteins, as the Office Action acknowledges (page 4), are well known and play an important role in the modulation of immune responses. Thus a B7-like protein has a "real world" use regulating innate immune responses and thus in treating various disease states and conditions. Applicants therefore contend that the asserted utility is substantial, and thus satisfies the second prong of a utility analysis.

Finally, the assertion of utility must be credible. The *Training Materials*, on page 5, define a "credible utility" as an assertion of utility that is believable to one of ordinary skill in the art based on the totality of evidence and reasoning provided. Furthermore, the *Training Materials* state that a credible utility is assessed from the standpoint of whether a person of ordinary skill in the art would

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accept that the recited or disclosed invention is currently available for such use. The instant application teaches nucleotide sequences encoding amino acid sequences for B7-like proteins (Figures 1-7). The instant application teaches that the human B7-like proteins are homologous to the murine B7-like protein (Figure 9) and further teaches that the homologous B7-like murine protein induces seminal vesicle hyperplasia in transgenic mice. Thus, based on the totality of the evidence, one of ordinary skill in the art would find the asserted utility, *i.e.*, the use as a B7-like protein, to be believable. Thus, Applicants contend that the asserted utility is credible to one of ordinary skill in the art, and satisfies the third prong of a utility analysis.

Applicants respectfully submit that because the instant application contains an assertion of a specific and substantial utility for the claimed invention that would be credible to one of skill in the art, the rejection under 35 U.S.C. § 101 should be withdrawn.

3. Claim Rejections Under 35 U.S.C. §112, first paragraph

(A) The Office Action asserts a rejection of claims 1-8, 10, 11, 48, and 57-59 under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in such a way as to enable one of skill in the art to which it pertains, or with which it is most clearly connected, to make and use the invention. The Office Action states that because the claimed invention is not supported by a specific and substantial asserted utility or a well-established utility, one skilled in the art would not know how to use the claimed invention.

Applicants first note the Claims 11 and 59 have been cancelled, thus obviating their rejection. Furthermore, Applicants contend that this ground of rejection stands or falls with the rejection asserted in the Office Action under 35 U.S.C. § 101. As set forth above, applicants have provided affirmative evidence that the asserted utility would be credible to one of ordinary skill in the art. Applicants respectfully contend that because the instant application in fact contains an assertion of a specific and substantial utility for the claimed invention that one of ordinary skill in the art would find to be credible, this rejection under 35 U.S.C. §112, first paragraph, is overcome, and should be withdrawn.

(B) The Office Action has maintained a rejection of Claim 59 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Applicants respectfully

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traverse this rejection, but nevertheless, solely in order to expedite prosecution of the instant application to allowance, have cancelled Claim 59, thus obviating its rejection.

(C) The Office Action has maintained a rejection of Claims 1-8, 10, 11, 48, and 57-59 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Applicants respectfully traverse this rejection.

Applicants first note the Claims 11 and 59 have been cancelled, thus obviating their rejection. Furthermore, Applicants respectfully assert that the claimed invention, as defined in the amended claims herein, is fully enabled. "The standard for determining whether the specification meets the enablement requirement... is [whether] the experimentation needed to practice the invention [is] undue or unreasonable..." *MPEP 2164.01.*

Applicants note that the invention defined by claim 1 is an isolated nucleic acid molecule comprising the nucleotide sequence as set forth in any of SEQ ID NO: 1, SEQ ID NO: 3, or SEQ ID NO: 5; a nucleotide sequence encoding a polypeptide as set forth in any of SEQ ID NO: 2, SEQ ID NO: 4, or SEQ ID NO: 6; a nucleotide sequence that hybridizes to the complement of the previously recited nucleotide sequences at 50°C in a hybridization buffer comprising 0.015M sodium chloride and 0.0015M sodium citrate; or the nucleotide sequence that is complementary to the previously recited nucleotide sequences. It would not require undue experimentation for one of ordinary skill in the art to practice the invention claimed in 1(a) as the specification explicitly discloses SEQ ID NOs: 1, 3, and 5. Furthermore, it would not require undue experimentation on the part of one of ordinary skill in the art to practice the invention defined by Claims 1(b) and 1(d), as one of ordinary skill in the art could readily discern what sequences encoded the polypeptides set forth in SEQ ID NOs: 2, 4, and 6, or what sequence was complimentary to these sequences.

With regard to Claim 1(c), Applicants contend that because one of ordinary skill in the art could readily determine whether a particular nucleotide sequence is encompassed by claim 1(c) by hybridizing the nucleotide sequence to the complement of one of the nucleotide sequences recited in claims 1(a)-(b) at 65°C in a hybridization buffer comprising 0.015 M sodium chloride and 0.0015 M sodium citrate, the genus of nucleotide sequences recited in claim 1(c) is enabled

Thus Applicants contend that the specification is fully enabling for Claim 1.

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Applicants next note that the invention defined by Claim 2 as amended is an isolated nucleic acid molecule comprising a region of the nucleotide sequence of any of SEQ ID NO: 1, SEQ ID NO: 3, or SEQ ID NO: 5 encoding a polypeptide fragment of at least about 25 amino acid residues; a region of the nucleotide sequence of any of SEQ ID NO: 1, SEQ ID NO: 3, or SEQ ID NO: 5 comprising a fragment of at least about 16 nucleotides; a nucleotide sequence that hybridizes to the complement of the previously recited nucleotide sequences at 50°C in a hybridization buffer comprising 0.015M sodium chloride and 0.0015M sodium citrate; or the nucleotide sequence that is complementary to the previously recited nucleotide sequences. One of skill in the art would readily be able to prepare the nucleic acid molecules of Claim 2 invention as these sequences are merely portions of the explicitly disclosed full length sequences, sequences that hybridize to these fragments, or the sequence complementary to these fragments. Applicants note that Claim 3 no longer recites conservative amino acid substitutions and thus Claim 3 is similarly enabled.

Finally, Applicants contend that dependent Claims 4-8, 10, 48, and 57-58 meet the requirements of 35 U.S.C. 112, first paragraph as it would not require undue experimentation for one of ordinary skill in the art to practice the invention defined in these claims in view of the teachings of the specification in combination with the knowledge of one of ordinary skill in the art.

Applicants, believing that the rejection of the pending claims based on 35 U.S.C. §112, first paragraph, have been overcome by amendment or traversed by argument, respectfully request that this ground of rejection be withdrawn.

4. Claim Rejections Under 35 U.S.C. §112, second paragraph

The Office Action asserts a rejection of claims 3-8, 10, 11, 48, and 57-59 under 35 U.S.C. § 112, second paragraph, as failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants first note that Claims 11 and 59 have been cancelled, thus obviating their rejection.

Specifically, the Office Action asserts that the claims are incomplete for omitting essential structural cooperative relationships of elements as related to the recitation of "at least one conservative amino acid substitution" and of "at least about 70% identical." Applicants note that the claims as amended no longer recite this language, thus obviating the rejection.

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The Office Action additionally asserts that Claim 10 is incomplete for omitting essential structural cooperative relationships of elements, and furthermore that the term "B7-like gene" in claim 10 is indefinite. In response, Applicants have amended Claim 10 and contend that as amended, Claim 10, and those that depend from it, comply with the requirements of 35 U.S.C. § 112, second paragraph.

5. Claim Rejections Under 35 U.S.C. §102

The Office Action has maintained a rejection of Claims 1-3 under 35 U.S.C. 102 as anticipated by Marra et al. or in the alternative by Taudien et al. Specifically, the Office Action asserts that these references disclose sequences that are complementary to SEQ ID NOs: 1, 3, or 5. For reasons set forth in previous office action responses, Applicants respectfully traverse this assertion.

Nevertheless, in order to fully clarify the nature of the claims, applicants have amended Claims 1-3 to recite "the nucleotide sequence that is complementary to the nucleotide sequence of..." As amended, the claims to not "embrace a nucleotide sequence that is complementary to any fragment of the nucleotide sequence," in the words of the Office Action (page 19). Thus applicants respectfully request reconsideration and withdraw of the rejection of Claims 1-3 under 35 U.S.C. 102.

CONCLUSIONS

Applicants respectfully contend that all conditions of patentability are met in the pending claims as amended. Allowance of the claims is thereby respectfully solicited.

If Examiner Whiteman believes it to be helpful, he is invited to contact the undersigned representative by telephone at (312) 913-0001.

Respectfully submitted,
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